

RECEIVED  
CENTRAL FAX CENTER

JUL 24 2006

## FULBRIGHT &amp; JAWORSKI L.L.P.

A REGISTERED LIMITED LIABILITY PARTNERSHIP  
600 CONGRESS AVENUE, SUITE 2400  
AUSTIN, TEXAS 78701-3271  
WWW.FULBRIGHT.COM

## FACSIMILE TRANSMISSION

DATE: July 24, 2006

MATTER NUMBER:

DEKM:055US /  
10201626

RECIPIENT(S):	FAX NO.:	PHONE NO.:
Commissioner for Patents U.S. Patent and Trademark Office	(571) 273-8300	

CERTIFICATE OF FACSIMILE TRANSMISSION  
37 C.F.R. § 1.8I certify that this correspondence is being transmitted to:  
Commissioner for Patents, P.O. Box 1450, Alexandria, VA  
22313-1450, facsimile number (571) 273-8300 on the date  
below:July 24, 2006  
Date  
Robert E. Hanson

FROM: Robert E. Hanson

USER ID: RH10056 FLOOR: 20

PHONE: (512) 536-3085

FAX: (512) 536-4598

RE: Serial No. 08/113,561

NUMBER OF PAGES WITH COVER PAGE: 22 Originals Will Not Follow

## Message:

Submitted for filing in Serial No. 08/113,561, please find a Response to Notification of Non-Compliant Appeal Brief and Supplemental Brief on Appeal.

## CAUTION - CONFIDENTIAL

THE INFORMATION CONTAINED IN THIS FACSIMILE IS CONFIDENTIAL AND MAY ALSO CONTAIN PRIVILEGED ATTORNEY-CLIENT INFORMATION OR WORK PRODUCT. THE INFORMATION IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHOM IT IS ADDRESSED. IF YOU ARE NOT THE INTENDED RECIPIENT, OR THE EMPLOYEE OR AGENT RESPONSIBLE TO DELIVER IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY USE, DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THE FACSIMILE IN ERROR, PLEASE IMMEDIATELY NOTIFY US BY TELEPHONE, AND RETURN THE ORIGINAL MESSAGE TO US AT THE ADDRESS ABOVE VIA THE U.S. POSTAL SERVICE. THANK YOU.

IF YOU DO NOT RECEIVE ALL OF THE PAGES, PLEASE CALL  
VIRGINIA VELAZQUEZ AT (512) 536-3077 AS SOON AS POSSIBLE.

JUL 24 2006

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Thomas R. Adams *et al.*

Serial No.: 08/113,561

Filed: August 25, 1993

For: METHODS AND COMPOSITIONS FOR  
THE PRODUCTION OF STABLY  
TRANSFORMED, FERTILE MONOCOT  
PLANTS AND CELLS THEREOF

Group Art Unit: 1638

Examiner: Fox, David T.

Atty. Dkt. No.: DEKM:055US

**CERTIFICATE OF FACSIMILE TRANSMISSION  
37 C.F.R. § 1.8**

I certify that this correspondence is being transmitted to:  
Commissioner for Patents, P.O. Box 1450, Alexandria, VA  
22313-1450, facsimile number (571) 273-8300 on the date  
below:

July 24, 2006  
Date

  
Robert E. Hanson

**RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Commissioner:

This paper is submitted in response to the Notification of Non-Compliant Appeal Brief dated June 26, 2006, for which the one-month date for response is July 26, 2006. This Notice was sent because the Brief did not include a "Related Proceedings Appendix" and thus it was asserted that the Brief was non-compliant. No fees are believed to be due in connection with the instant paper, however, should such fees be due, consider this paragraph a request and authorization to withdraw the appropriate fee under 37 C.F.R. §§ 1.16 to 1.21 from Fulbright & Jaworski, L.L.P. Account No. 50-1212/ DEKM:055US.

25678596.1

**RESPONSE**

Applicants submit herewith a Supplemental Appeal Brief with the headings and items as required under 37 C.F.R. 41.37(c) and 37 C.F.R. 41.37(c)(1)(x), including the blank section under "Related Proceedings Appendix." The Related Appeals and Interferences section has also been updated.

The examiner is invited to contact the undersigned (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Robert E. Hanson  
Reg. No. 42,628  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 536-3085  
(512) 536-4598 (facsimile)

Date: July 24, 2006

RECEIVED  
CENTRAL FAX CENTER

JUL 24 2006

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Thomas R. Adams *et al.*

Serial No.: 08/113,561

Filed: August 25, 1993

For: METHODS AND COMPOSITIONS FOR  
THE PRODUCTION OF STABLY  
TRANSFORMED, FERTILE MONOCOT  
PLANTS AND CELLS THEREOF

Group Art Unit: 1638

Examiner: Fox, David T.

Atty. Dkt. No.: DEKM:055US

CERTIFICATE OF FACSIMILE TRANSMISSION  
37 C.F.R. § 1.8

I certify that this correspondence is being transmitted to:  
Commissioner for Patents, P.O. Box 1450, Alexandria, VA  
22313-1450, facsimile number (571) 273-8300 on the date  
below:

July 24, 2006  
Date

  
Robert E. Hanson

**SUPPLEMENTAL BRIEF ON APPEAL**

25678606.1

**TABLE OF CONTENTS**

I.	REAL PARTY IN INTEREST.....	2
II.	RELATED APPEALS AND INTERFERENCES .....	2
III.	STATUS OF THE CLAIMS .....	2
IV.	STATUS OF AMENDMENTS.....	2
V.	SUMMARY OF CLAIMED SUBJECT MATTER.....	2
VI.	GROUND OF REJECTION TO BE REVIEWED ON APPEAL .....	3
VII.	ARGUMENT.....	3
A.	The Claims Meet The Written Requirement Under 35 U.S.C. §112, First Paragraph.....	3
1.	The Rejection is Legally Unsupported .....	4
2.	Fatty Acid Desaturases Were Well Known in the Art.....	7
B.	The Claims Are Enabled.....	10
1.	The Rejection is Legally Unsupported .....	10
2.	Appellants Have Affirmatively Established the Enablement of the Claims .....	11
3.	The Working Examples Demonstrate Enablement of the Claims.....	13
C.	Conclusion.....	14
VIII.	CLAIMS APPENDIX .....	15
IX.	EVIDENCE APPENDIX .....	16
X.	RELATED PROCEEDINGS APPENDIX.....	17

**RECEIVED**  
**CENTRAL FAX CENTER****JUL 24 2006****PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re Application of:  
Thomas R. Adams *et al.*

Serial No.: 08/113,561

Filed: August 25, 1993

For: METHODS AND COMPOSITIONS FOR  
THE PRODUCTION OF STABLY  
TRANSFORMED, FERTILE MONOCOT  
PLANTS AND CELLS THEREOF

Group Art Unit: 1638

Examiner: Fox, David T.

Atty. Dkt. No.: DEKM:055US

**SUPPLEMENTAL BRIEF ON APPEAL****Mail Stop Appeal Brief - Patents**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit a Supplemental Appeal Brief pursuant a Notification of Non-Compliant Appeal Brief dated June 26, 2006. No fees are believed to be due in connection with the this filing, however, should any additional fees become due under 37 C.F.R. §§ 1.16 to 1.21 for any reason relating to the enclosed materials, or should an overpayment be made, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/DEKM:055US.

**I. REAL PARTY IN INTEREST**

The real party in interest is Monsanto Company, the parent company of assignee DeKalb Genetics Corp.

**II. RELATED APPEALS AND INTERFERENCES**

Appeals have been filed by the Real Party in Interest, but have not yet been decided by the Board, in U.S. Patent Application Ser. No. 09/732,439 and 09/081,416. U.S. Patent Application Serial No. 09/732,439 is a divisional of Ser. No. 08/599,714, which is a continuation-in-part of 08/113,561. U.S. Patent Application Serial No. 09/081,416 is a divisional of 08/113,561.

**III. STATUS OF THE CLAIMS**

Claims 1-68 were filed. Claims 1, 5-66 and 68 were canceled. Claims 2-4 and 67 are therefore currently pending and are the subject of this appeal. A copy of the appealed claims is attached as Claims Appendix.

**IV. STATUS OF AMENDMENTS**

No amendments were made subsequent to the Final Office Action.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

The invention relates to genetically transformed monocotyledonous plants. Specification at page 3, lines 10-13. More particularly, it relates to fertile, transgenic maize plants transformed with a DNA sequence encoding a fatty acid desaturase gene, wherein the DNA sequence is capable of being transmitted to subsequent plant progeny and is expressed. Specification at page

306. Expression of the fatty acid desaturase yields plants with altered seed oil properties.  
Specification at page 45, lines 18-19.

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

(A) Are claims 2-4 and 67 properly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement?

(B) Are claims 2-4 and 67 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled by the specification?

Appellants note that the Final Office Action rejected claims 2 and 3 as indefinite under 35 U.S.C. §112, second paragraph, for depending upon a canceled claim. Appellants intend to correct the error by amendment upon the allowance of the case or reopening of prosecution and thus are not appealing the rejection.

## **VII. ARGUMENT**

### **A. The Claims Meet The Written Requirement Under 35 U.S.C. §112, First Paragraph**

The Examiner asserts that the claims lack an adequate written description under 35 U.S.C. §112, first paragraph, on the basis that the fatty acid desaturase genes incorporated into the claimed plants are not adequately described. For example, it was stated that claims drawn to maize plants transformed with a particular gene are inadequately described if the starting material, namely the gene, is itself inadequately described. Action dated May 13, 2004 at p.4. *Eli Lilly* was cited in this regard for the proposition that a claimed invention must be defined by a precise definition, such as by structure, formula, *etc.*, and MPEP §2163, p.156 was cited for the principle that a biomolecule cannot be defined merely by function when the function is not correlated with a structure. *Id.* at p. 4-5. In the Final Office Action the Examiner added a



citation to the *University of Rochester* district court case for the holding that method claims are properly subjected to a written description rejection if the starting material required by the method is inadequately described. *University of Rochester v. G.D. Searle & Co., Inc.*, 249 F. Supp. 2d 216; 68 U.S.P.Q.2D 1424 (D.N.Y, 2003). Final Action at p. 3-4. Finally, the Examiner asserted that desaturases were not known, stating that many of the earlier-submitted references were published after August 1993. Final Action at p. 4. As explained below, none of these arguments properly supports the rejection and thus the rejection should be reversed.

### 1. The Rejection is Legally Unsupported

The cases cited by the Examiner involve situations in which written was found lacking because the point of novelty was not described. In contrast, the fatty acid desaturase genes alleged here to have not been described were known in the art. The Examiner has nonetheless examined the claims as if they were directed to fatty acid desaturase genes *per se*. This position is contrary to the cited cases and well settled precedent holding that the specification need not disclose what is well-known to those skilled in the art and *preferably omits* what is well-known and already available to the public. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986).

The distinction between the current situation and the cited cases is illustrated by comparing the facts at issue. In *Eli Lilly*, for example, the subject patent claimed a novel human insulin-encoding cDNA sequence but disclosed only a rodent sequence. A lack of written description was found because the specification failed to describe the human sequence being claimed. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1405 (Fed. Cir. 1997). In *Amgen v. Chugai*, cited by the Examiner on page 5 of the Office Action dated May 13, 2004, the issue was what constituted conception of an invention directed to isolated DNA sequences encoding human erythropoietin. *Amgen Inc. v.*

*Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). The Federal Circuit rejected an accused infringer's accusation of prior invention under 35 U.S.C. §102(g) based on conception of a generalized approach for screening a DNA library because the methodology was not a definite and permanent idea of the complete and operative invention without knowledge of the structure of the gene sequence. *Id.* at 1206. The issue was therefore conception of a novel nucleic acid sequence, not description of a known nucleic acid sequence.

The Final Office Action attempted to supplement the foregoing legal shortcomings of the written description rejection by citing two additional cases, the *University of Rochester* district court case of March 2003, Order No. 00-CV06161L dated March 5, 2003, and the *Bayer v. Housey* Federal Circuit case. 340 F.3d 1367, 68 U.S.P.Q.2d 1001 (Fed. Cir. 2003); Final Office Action at p. 3-5. Neither of these cases is on point to the current situation as well.

At issue in the *University of Rochester* case were claims directed to a method of selectively inhibiting the enzyme COX-2 by administering a non-steroidal compound that selectively inhibits activity of the COX-2 gene product. The district court found that the patent at issue was invalid for failure to comply with the written description requirement because the applicants did not disclose a non-steroidal compound that selectively inhibits COX-2 and provided no specific suggestion how it could be made. 249 F. Supp. 2d at 224. The case was taken on appeal and the Federal Circuit affirmed. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (Fed. Cir., Feb. 13, 2004). The Federal Circuit noted in particular that the patent was invalid for written description because the required compound, *e.g.*, an inhibitor of COX-2, was not disclosed in the application and there was *no pre-existing awareness in the art* of a compound exhibiting the claimed activity. *Id.* at 927. The court emphasized that what was not described or known was what in fact was essential to the claimed

invention - a compound that inhibits COX-2 – and that the inventors had neither possession nor knowledge of such a compound. *Id.* This authority therefore does not relate to the situation where a known compound is used to make a new claimed product. *Rochester* and the corresponding line of authority are therefore inapposite to the current situation and provide no support for the rejection.

The Final Office Action also cited *Bayer v. Housey*, 340 F.3d 1367, 68 U.S.P.Q.2d 1001 (Fed. Cir. 2003) for the proposition that “processes of identification and generation of data are not steps in the manufacture of a final [drug] product.” Final Action at p. 4. However, the issue decided in this case and referenced with regard to steps in the manufacture of a drug product was patent infringement under 35 U.S.C. §271(g), not written description. The case turned on the meaning of “product” under 35 U.S.C. 271(g) and whether this covered the importation of information gained from patented drug screening assays. *Id.* at 1371. The case therefore has no relevance to the current written description rejection and provides no support for the rejections made.

In sum, no legal basis has been provided for maintaining the written description rejection. The rejection made is directly contrary to well settled legal precedent holding that what is known in the art need not be described with particularity and is in fact preferably omitted from the specification. *See, e.g., See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986). Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act (“APA”). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko*, 258 F.3d 1379, 59 USPQ2d 1693 (Fed. Cir. 2001). An Examiner’s position on Appeal must be supported by “substantial evidence” within the record pursuant to the APA in order to be upheld by the Board of Patent

Appeals and Interferences. See *In re Gartside*, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). As the current rejections are unsupported in fact or law, the standards of the APA have not been met. Reversal of the rejection is thus respectfully requested.

## 2. Fatty Acid Desaturases Were Well Known in the Art

Unsupported conclusions to the contrary in the Final Office Action notwithstanding, numerous fatty acid desaturases were known and found in the literature prior to the August, 1993 filing date. Among these, McDonough *et al.* (Exhibit A) ("Specificity of unsaturated fatty acid-regulated expression of the *Saccharomyces cerevisiae* OLE1 gene."; *J Biol Chem.* 1992 Mar 25;267(9):5931-6) describe a *Saccharomyces cerevisiae* OLE1 gene encoding delta-9 fatty acid desaturase, an enzyme which forms the monounsaturated palmitoleic (16:1) and oleic (18:1) fatty acids from palmitoyl (16:0) or stearoyl (18:0) CoA. Fox *et al.* (Exhibit B) ("Stearoyl-acyl carrier protein delta 9 desaturase from *Ricinus communis* is a diiron-oxo protein." *Proc Natl Acad Sci U S A.* 1993 Mar 15;90(6):2486-90) describe a gene encoding a stearoyl-acyl carrier protein delta 9 desaturase from castor that was expressed in *Escherichia coli*. The authors compared the primary structures of catalytically diverse proteins to identify conserved amino acid motifs involved in eukaryotic fatty acid desaturation.

Reddy *et al.* (Abstract - Exhibit C) ("Isolation of a delta 6-desaturase gene from the cyanobacterium *Synechocystis* sp. strain PCC 6803 by gain-of-function expression in *Anabaena* sp. strain PCC 7120" *Plant Mol Biol.* 1993 May;22(2):293-300) describe the cloning of a delta 6-desaturase from the cyanobacteria *Synechocystis* that is responsible for the conversion of linoleic acid (18:2) to gamma-linolenic acid (18:3 gamma). A delta 12-desaturase gene linked to the delta 6-desaturase gene was also identified and expression of the delta 6- and delta 12-desaturases in *Synechococcus* deficient in both desaturases carried out to result in the production of linoleic acid and gamma-linolenic acid. Arondel *et al.* (Abstract - Exhibit D) ("Map-based

cloning of a gene controlling omega-3 fatty acid desaturation in *Arabidopsis*." *Science*. 1992 Nov 20;258(5086):1353-5) describe a gene from *Arabidopsis thaliana* that encodes an omega-3 desaturase. Transgenic tissues of both mutant and wild-type plants of the model dicotyledonous plant *Arabidopsis thaliana* were found to have significantly increased amounts of the fatty acid produced by this desaturase. PCT Application Publ. No. WO 91/13972 describes plant  $\Delta 9$  desaturases (**Exhibit E**), European Patent Application Publ. No. EP 0616644 describes soybean and *Brassica*  $\Delta 15$  desaturases (**Exhibit F**), and European Patent Application Publ. No. 0537178 describes soybean stearyl-ACP desaturases (**Exhibit G**).

Appellants therefore have shown that numerous examples of fatty acid desaturases were found in the literature and available to the public before the August 25, 1993 filing date. For example, each of the references submitted as Exhibits A-G were published before August 25, 1993. These examples demonstrate that genes encoding fatty acid desaturases were well known in the art.

The specification itself further describes in detail how such fatty acid desaturase genes alter grain composition traits. For example, it is taught that genes may be introduced to alter the balance of fatty acids present in seed oil providing a more healthful or nutritive feedstuff, and may be used to block expression of enzymes involved in fatty acid biosynthesis to alter proportions of fatty acids present. As explained, changes in oil properties may be achieved by altering the type, level, or lipid arrangement of the fatty acids present in the oil. Among representative catalytic steps mentioned for modification include the desaturations from stearic to oleic acid and oleic to linolenic acid resulting in the respective accumulations of stearic and oleic acids.

These examples demonstrate that genes encoding fatty acid desaturases were well known in the art and that the specification fully describes their use in altering grain composition traits. What was not known in the prior art was that they could be expressed for benefit in maize. The inventors have overcome this deficiency and for the first time describe methods enabling the expression of desaturases to alter maize grain composition traits. No assertion has been made that the transformation of maize and transgenic maize plants generally have not been described. The specification contains numerous descriptions of transgenic plants and working examples showing the introduction of transgenes into plants.

The specification, for example, indicates after Table 8 that fertile plants were obtained from 267 different transgenic lines produced. In Table 9, the specification describes the creation of numerous transgenic maize plants with a variety of different genes using many different regulatory elements. For example, the table shows the creation of R0 transgenic plants and confirmation of transgene expression in these plants and progeny using the following genes: a *uidA* reporter gene, a *bar* selectable marker gene conferring herbicide tolerance, a *hyg* gene conferring resistance to hygromycin, an *aroA* gene conferring tolerance to the herbicide glyphosate, a *Bacillus thuringiensis* endotoxin gene, and a Z10 altered seed storage protein. The Table further shows that transgenic maize callus was obtained transformed with a C1 anthocyanin pigmentation gene, a *lux* luciferase reporter gene, potato and tomato *pinII* proteinase inhibitor genes conferring insect resistance, an *mtlD* protein conferring enhanced stress resistance and a *deh* gene conferring resistance to dalapon herbicide. While an actual reduction to practice for fatty acid desaturase genes is not described, it is well settled that Appellants need not have done so. This is underscored by the numerous working examples in the specification and detailed teachings in the specification fully establishing possession of the invention.

In conclusion, Appellants have affirmatively established on the record a written description for the claimed subject matter and demonstrated the lack of any legal basis for doubting the sufficiency of the description. Reversal of the rejection is thus respectfully requested.

**B. The Claims Are Enabled**

The Examiner rejected claims 2-4 and 67-68 under 35 U.S.C. §112, first paragraph, as not enabled for fatty acid desaturase genes or expression of the genes in plants. For example, the Examiner asserted that evidence that desaturase genes were well known in the art was non-persuasive by citing *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 42 USPQ2d 1001 (Fed. Cir. 1997) for the proposition that the specification, not the knowledge of one skilled in the art, must supply the enabling aspects of the invention. Declaratory evidence submitted by Appellants showing that desaturase genes successfully express in maize plants was disregarded as "insufficient to demonstrate that the specification enabled the claimed invention." As explained below, the rejection is unsupported and should be reversed.

**1. The Rejection is Legally Unsupported**

Appellants first note that the Action does not contest the fact that the specification fully enables transformation of maize with heterologous genes. Appellants further note that the claims are directed to maize plants transformed with desaturase genes, not fatty acid desaturase genes *per se*, as these sequences are known. The authority cited in the Final Action does not relate to such a situation. For example, in *Genentech* the subject patent claimed a method of producing hGH hormone using a cleavable fusion expression. *Id.* at 1365. A lack of enablement was found because the specification did "not describe in any detail how to make hGH using cleavable

fusion expression.” *Id.* The court agreed that the specification need not disclose what is already well known in the art, holding that it is “the specification, not the knowledge of one skilled in the art, that must supply the *novel* aspects of an invention in order to constitute adequate enablement.” *Id.* at 1366 (emphasis added). In the current application, what is *novel* is a composition of maize plants transformed with desaturase genes, not the known desaturases themselves. The *Genentech* case is therefore inapposite to this situation.

**2. Appellants Have Affirmatively Established the Enablement of the Claims**

Appellants have further presented affirmative evidence demonstrating enablement in the form of the Declaration Dr. Virginia Ursin. **Exhibit H.** Dr. Ursin describes studies showing that the expression of  $\Delta 6$  and  $\Delta 15$  desaturases in maize results in an alteration in the fatty acid profile of corresponding transgenic plants that renders them identifiable over the corresponding non-transgenic plants. *Id.* at ¶6-7. As explained, the results showed that the *two* desaturases were expressed and that alteration of fatty acid profiles in maize occurs in a predictable manner that is consistent with the enzymatic activity of the fatty acid desaturase that is introduced. *Id.* at ¶7. This evidence therefore establishes that expression of a fatty acid desaturase in maize would in fact occur in a predictable manner that distinguishes transgenic plants from corresponding non-transgenic plants.

The Final Action dismissed this evidence as non-persuasive because Dr. Ursin used a transformation technique “which is not the technique disclosed by Applicant,” and because Dr. Ursin “utilized fatty acid desaturase genes which were disclosed... well after the effective filing date.” Final Action at p. 6. These statements, which Appellants take as true for the purposes of this argument only, were used as the basis of the Examiner’s conclusion that the Declaration “is insufficient to demonstrate that the specification enabled the claimed invention.” However, the



statements made by the Examiner do not justify maintenance of the rejection. First, the Examiner has not contested the enablement of the application for transformation of maize plants and the transformation method is irrelevant to whether a fatty acid desaturase gene is expressed. The goal is to introduce a foreign gene and, the specification having already enabled this, the method used is irrelevant. Whether *Agrobacterium*-mediated transformation or microprojectile bombardment was used is thus irrelevant.

With regard to the public availability of the desaturase genes used by Dr. Ursin, this also does not negative enablement. While the  $\Delta 6$  and  $\Delta 15$  genes expressed in maize were not the same as the fatty acid desaturase genes disclosed in Exhibits A-G, the studies show that fatty acid desaturases are expressed consistent with their known enzymatic characteristics in transgenic maize. Further, other  $\Delta 6$  and  $\Delta 15$  desaturases were known as shown in Exhibits C and F. As explained by Dr. Ursin, the studies disclosed in the Declaration:

demonstrated that expression of a fatty acid desaturase gene in maize alters the fatty acid profile in a manner that renders the transgenic plants identifiable over corresponding non-transgenic plants. The results further confirm that the alteration of fatty acid profiles in maize occurs in a predictable manner that is consistent with the enzymatic activity of the fatty acid desaturase that is introduced into a given maize plant.

The Declaration therefore establishes that fatty acid desaturase gene expression in maize occurs in a predictable manner and serves to distinguish transgenic plants from corresponding non-transgenic plants. Furthermore, with regard to the asserted non-availability of desaturases, it has already been shown above that each of the fatty acid desaturases disclosed in Exhibits A-G were available as of August 25, 1993, and thus can be relied upon consistent with *In re Glass*.

Finally, the Examiner attempted to support the foregoing rejection by stating that Appellants in the bottom paragraph of page 9 of the Response to Office Action dated October 13,

2004 acknowledged the unpredictability of the claimed invention. A review of the Response, however, demonstrates that it refers only to the teachings of the cited prior art, not the predictability of the invention in view of the specification teaching as it is relevant to enablement. As explained in the Response, the cited prior art was entirely prophetic with regard to creation of a single transgenic maize plant. In contrast and as illustrated further in §VII.B.3 below, the specification reports production of fertile transgenic plants from 267 different transgenic lines, and reports the production of progeny plants containing and expressing numerous foreign genes. One of skill in the art would have therefore been without any reasonable expectation in arriving at the inventions based on the prior art, but would have been fully enabled for practice of the claimed invention upon possession of the specification.

### 3. The Working Examples Demonstrate Enablement of the Claims

The specification contains working examples demonstrating the production of transgenic plants from numerous different transgenes and demonstrates confirmation of the expression of these transgenes. For example, after Table 8 the specification discloses that fertile transgenic plants were obtained from 267 different transgenic lines. In Table 9, the specification describes the creation of transgenic maize plants with a variety of different genes using different regulatory elements. For example, Table 9 shows the creation of R0 transgenic plants and progeny in which transgene presence *and expression* have been confirmed for a diverse collection of transgenes including: a *uidA* reporter gene, a *bar* selectable marker gene conferring herbicide tolerance, a *hyg* gene conferring resistance to hygromycin, an *aroA* gene conferring tolerance to the herbicide glyphosate, a *Bacillus thuringiensis* endotoxin gene, and a Z10 altered seed storage protein. The Table further shows that transgenic maize callus was obtained transformed with a C1 anthocyanin pigmentation gene, a *lux* luciferase reporter gene, potato and tomato *pinII* proteinase

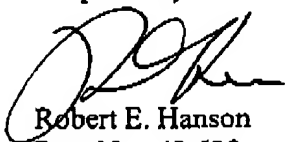
inhibitor genes conferring insect resistance, an *mtlD* protein conferring enhanced stress resistance and a *deh* gene conferring resistance to dalapon herbicide. These examples coupled with the evidence presented above fully demonstrate the enablement of the claims for transgenic expression of fatty acid desaturases.

In conclusion, Appellants have affirmatively presented evidence on the record establishing enablement and at the same time demonstrated the lack of any legal basis for rejecting the claims. Reversal of the rejection is thus respectfully requested.

C. Conclusion

It is respectfully submitted, in light of the above, that none of the claims are properly rejected. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



Robert E. Hanson  
Reg. No. 42,628  
Attorney for Appellants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 536-3085

Date: July 24, 2006

**VIII. CLAIMS APPENDIX**

1. (Canceled)
2. (Previously amended) Cells obtained from the plant of claim 67, wherein said cells comprise the DNA composition.
3. (Previously amended) Progeny of the plant of claim 67, wherein said progeny comprise the DNA composition.
4. (Previously amended) Seeds obtained from the plant of claim 3, wherein said seeds comprise the DNA composition.
- 5-66. (Canceled)
67. (Previously amended) A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding a grain composition trait comprising a fatty acid desaturase gene so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.
68. (Canceled)

**IX. EVIDENCE APPENDIX**

Exhibits A – H were previously submitted with the our Appeal Brief.

Exhibit A: McDonough *et al.* (*J Biol Chem.* 1992 Mar 25;267(9):5931-6); submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit B: Fox *et al.* (*Proc Natl Acad Sci U S A.* 1993 Mar 15;90(6):2486-90); submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit C: Reddy *et al.* (*Plant Mol Biol.* 1993 May;22(2):293-300); submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit D: Arondel *et al.* (*Science.* 1992 Nov 20;258(5086):1353-5); submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit E: PCT Application Publ. No. WO 91/13972; submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit F: European Patent Application Publ. No. EP 0616644; submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit G: European Patent Application Publ. No. 0537178; submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action

Exhibit H: Declaration of Dr. Virginia Ursin; submitted with Response to Office Action Dated October 13, 2004 and entered by Final Office Action.

**X. RELATED PROCEEDINGS APPENDIX**

None

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**